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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/048,103

03/13/2008

Hideki Ishihara

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7590

01/24/2017

BGL

P.O. BOX 10395

CHICAGO, IL 60610

EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

01/24/2017

PAPER

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* HIDEKI ISHIHARA and YASUHIRO KOUCHI<sup>1</sup>

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Appeal 2015-007984  
Application 12/048,103  
Technology Center 1600

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Before JEFFREY N. FREDMAN, RYAN H. FLAX, and  
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an apparatus for supporting diagnosis of cancer, which have been rejected as being directed to non-statutory subject matter and as being obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

In diagnosing cancer, “using a specific measurement value . . . as the index, a specific reference value is normally set as the index, and various determinations are made based on the comparison between such reference

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<sup>1</sup> Appellants identify the Real Party in Interest as Sysmex Corp. (Appeal Br. 2.)

value and the measurement value obtained by measuring the sample collected from the patient.” (Spec. ¶ 5.) The index measurement value is “acquired from a great number of patients, the information (sample data) are accumulated as library information, and a value at which determination can be made at best accuracy based on the library information is set as the reference value.” (Spec. ¶ 6.) However, “the reference value sometimes needs to be changed when the library information is updated or added.” (Spec. ¶ 7.) The Appellants’ invention provides “a diagnosis support apparatus of cancer in which the reference value of the index used in diagnosing cancer can be changed by the user.” (Spec. ¶ 8.)

Claims 1–9 and 11–14 are on appeal.<sup>2</sup> Claim 1 is representative and reads as follows:

1. An apparatus for supporting diagnosis of cancer, comprising:
  - a display;
  - a processor;
  - a memory for storing a plurality of sample data, each of the sample data having a sample measurement value of a predetermined item of a prior cancer patient and sample clinical information of the prior cancer patient after extirpation of a malignant tumor that are associated with each other, and a predetermined reference value associated with sample measurement values of the plurality of sample data; and
  - a non-transitory computer readable storage medium having stored therein data representing instructions executable by the processor for performing steps of:

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<sup>2</sup> Claim 10 is also pending, but stands “withdrawn from further consideration pursuant to 37 CFR [§] 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.” (Final Action 2.)

- (a) acquiring a measurement value of the predetermined item from a malignant tumor collected from a cancer patient;
- (b) displaying on a reference value updating screen a sample data chart based on the sample data stored in the memory;
- (c) displaying a reference value indicator at a location on the sample data chart corresponding to the reference value;
- (d) associating each of a plurality of regions of sample data partitioned by the reference value with one of a plurality of diagnosis support information of cancer;
- (e) generating on the reference value updating screen a graph representing a disease free survival for at least one of the plurality of diagnosis support information of cancer based on sample data contained in regions associated with the at least one of the plurality of diagnosis support information of cancer;
- (f) accepting change of the reference value by a user;
- (g) when the reference value is changed, re-generating on the reference value updating screen the graph representing a disease free survival using the changed reference value so as to allow the user to change the reference value until a desired graph representing a disease free survival is generated;
- (h) determining a diagnosis support information of cancer for the cancer patient by comparing the acquired measurement value and the changed reference value; and
- (i) storing the changed reference value in the memory.

(Appeal Br. 20–21.)

The following grounds of rejection by the Examiner are before us on review:

Claims 1–9 and 11–14 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1–9 and 11–14 under 35 U.S.C. § 103 as unpatentable over Gehrman,<sup>3</sup> or Kattan,<sup>4</sup> or Kim,<sup>5</sup> and Killoren Clark,<sup>6</sup> or Kenmochi,<sup>7</sup> and/or Nozaki,<sup>8</sup> and Kohrt,<sup>9</sup> or Ravdin.<sup>10</sup>

## DISCUSSION

### *Non-Statutory Subject Matter*

The Examiner finds that claim 1 is “directed to the abstract idea of acquiring measurements, displaying values, associating values, and updating data in a manner that does not add anything to the data manipulation, i.e. the abstract idea of a mathematical relationship or manipulation.” (Final Action 3; Ans. 2–3.) The Examiner further finds that limitations, when viewed singly or in combination, “amount[] to no more than: mere instructions to

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<sup>3</sup> Gehrman et al., US 2009/0222387 A1, published Sept. 3, 2009.

<sup>4</sup> Kattan et al., US 2005/0019798 A1, published Jan. 27, 2005.

<sup>5</sup> Kim et al., US 2005/0181361 A1, published Aug. 18, 2005.

<sup>6</sup> Killoren Clark et al., US 7,912,674 B2, issued Mar. 22, 2011.

<sup>7</sup> Kenmochi et al., US 7,459,644 B2, issued Dec. 2, 2008.

<sup>8</sup> Nozaki et al., US 7,031,847 B1, issued Apr. 18, 2006.

<sup>9</sup> Holbrook E. Kohrt et al., *Profile of Immune Cells in Axillary Lymph Nodes Predicts Disease-Free Survival in Breast Cancer*, 2 PLoS Medicine 9, 0904–0919 (2005).

<sup>10</sup> Peter M. Ravdin et al., *Computer Program to Assist in Making Decisions About Adjuvant Therapy for Women With Early Breast Cancer*, 19 J. Clin. Oncol. 4, 980–991 (2001).

implement such an abstract idea on a computer and the recitation of a generic computer that serves to perform such functions” and, as such, “do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea.” (*Id.*)

We agree with the Examiner’s conclusion that claim 1 is unpatentable as being directed to non-statutory subject matter.

Appellants do not contest that claim 1 is directed to an abstract idea. (Appeal Br. 11.) As Appellants concede, the claim is directed to “manipulation of data for cancer diagnosis.” (Appeal Br. 12.)<sup>11</sup> The focus of claim 1 is on collecting information, analyzing it, and displaying certain results of the collection and analysis to support cancer diagnosis.

Appellants contend, however, that claim 1 recites elements “that amount to significantly more than the abstract idea.” (Appeal Br. 11; Reply Br. 2–3.) Appellants point to claim 1’s recitation of generating, and re-generating, when a reference value is changed, a graph representing a disease-free survival on the same screen as a sample data chart and reference

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<sup>11</sup> We note that our reviewing court has recently held system claims for detecting improper access of a patient’s protected health information that include “a user interface” and a microprocessor to be patent ineligible abstract ideas. *FairWarning IP LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1097 (Fed. Cir. 2016). The Court explained that “limiting the claims to the computer field does not alone transform them into a patent-eligible application. *See Alice*, 134 S. Ct. at 2358.” *Id.* The Court held that:

[t]he limitations added in FairWarning’s system claims merely graft generic computer components onto otherwise-ineligible method claims. As such, these claims are patent ineligible along with claim 1 and its dependents.

*Id.* at 1096.

value indicator graph as being unconventional steps for achieving cancer diagnosis. (*Id.*) According to Appellants, these graphing elements “add significantly more than mere instructions to implement the abstract idea of acquiring measurements, displaying values, associating values, and updating data or the abstract idea of mathematical manipulation of data on a computer.” (*Id.*) We do not find Appellants’ argument persuasive.

As our reviewing court recently noted, “[p]recedent has recognized that specific technologic modifications to solve a problem or improve the functioning of a known system generally produce patent-eligible subject matter.” *Trading Techs. Int’l, Inc. v. CQG, Inc.*, Appeal No. 2016-1616, slip op. 7, (Jan. 18, 2017) (non-precedential). We do not find that to be the case here. Appellants do not assert that claim 1 requires an arguably inventive device or technique for displaying information or new techniques for analyzing information. Thus, this case is unlike *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014), finding an inventive concept in modification of conventional mechanics behind website display to produce dual-source integrated hybrid display.

Appellants also do not argue the invention is a software-based invention that improves the performance of the computer system itself. Thus, this case is also unlike *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016), finding an inventive concept in the ordered combination of limitations providing for “the installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user.”

We note that “[c]laims directed to the ‘process of gathering and analyzing information of a specified content, then displaying the results,’ without ‘any particular assertedly inventive technology for performing those functions,’ were held ineligible in *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016).” *Trading Techs.*, slip op. 8. We find claim 1 to be analogous to that held patent ineligible in *Electric Power*.

Appellants do not describe how the mere act of providing a visual representation of the data manipulation in a graph is transformative, or how doing so on the same screen as other visual representations of stored data is transformative. (*See e.g.*, Ans. 15–16.) “Merely requiring the selection and manipulation of information—to provide a ‘humanly comprehensible’ amount of information useful for users, . . . —by itself does not transform the otherwise-abstract processes of information collection and analysis.” *Electric Power*, 830 F.3d at 1355. Appellants’ claimed presentation of graphical information before underlying information is updated and redisplaying graphical information based on the update of underlying information does not provide any technological advance to the process of analyzing the data or displaying it. For example, there are not any limited and new mathematical rules applied to the data or an improvement in the way the system components operate to display in graphical format the results of the manipulation of the data. Thus, we agree with the Examiner that the claim limitations, analyzed alone and in combination, fail to add “something more” to “transform” the claimed (undisputed) abstract idea of collecting and analyzing information to determine disease-free survival in support of

cancer diagnoses into “a patent-eligible application.” *See Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347, 2354, 2357 (2014).

Appellants’ argument that *Smartgene Inc. v. Advanced Biological Laboratories, SA*, No. 2013-1186 (Fed. Cir. 2014) (non-precedential), cited by the Examiner is not controlling because steps (e) and (g) of the claims are not “action[s] that doctors can perform in their heads” (Reply Br. 3) is inapposite for the reasons discussed above. That is, the governing case-law for patent eligibility under 101 does not rest on whether or not limitations were or were not previously performed in the heads of certain populations.

Moreover, whether or not doctors perform steps (e) and (g) in their head is immaterial. As the Examiner noted, *Smartgene* “inform[s] that claims setting forth the comparison of new and stored information and using rules to identify medical options are not patent eligible because the claims do nothing more than call on a computing device with basic functionality for comparing stored and input data and rules to do what doctors routinely do.” (Ans. 14.) In the instant case, the Examiner noted that graphing a disease-free state is “routine in the art” and is a step “routinely performed by general purpose computers.” (*Id.*) In other words, the Examiner’s position is that the claimed steps did not rely on an inventive device or technique for displaying information or new techniques for analyzing information. As discussed above, this is not a point on which the Appellants disagree.

Appellants’ argument that there is no preemption concern because claim 1 is limited to cancer diagnosis and steps (e) and (g) are not necessary for cancer diagnosis (Appeal Br. 12) is also not persuasive. “[T]he absence of complete preemption does not demonstrate patent eligibility.” *Ariosa*

*Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015).

“Where a patent’s claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.” *Id.*

Claims 2–9 and 11–14 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

### *Obviousness*

The Examiner finds that “Gehrmann et al, Kattan et al, or Kim et al. are exemplary references teaching computerized systems that execute methods that acquire measurement value and clinical information, compare the measurement and reference values, and display for presenting reference and measurement data.” (Final Action 7; Ans. 6–8.) The Examiner finds that “it would have been *prima facie* obvious to one skilled in the art that a reference value is not permanent and may be changed by a user upon considering data that establish a reference value.” (Final Action 9; Ans. 8, emphasis omitted.) In support of that conclusion, the Examiner cites Killoren Clark and Kenmochi as teaching processing measurements using a reference value that is updatable allowing for re-interpretation of records based on the change. (*Id.*) The Examiner finds that Nozaki teaches data analysis in the cancer field where the range of measurement data displayed is changed based on changing a reference value. (Final Action 10; Ans. 9.) The Examiner determines that it would have been predictable to one of ordinary skill in the art to have applied rescaling based on a changed reference value in cancer data analysis in light of the foregoing. (*Id.*)

The Examiner finds, that, while the foregoing references do not explicitly teach inclusion of associating specific data areas with diagnosis support and generating graphs representing disease-free survival, such would have been obvious to one of ordinary skill in the art based on the teachings of Kohrt and Ravdin. (Final Action 10; Ans. 9–10.) According to the Examiner, “Kohrt et al. and Ravdin et al. teach that it was standard at the time of the invention to have included disease free survival estimates, in the form of graphs or tables, to cancer data based upon comparisons with sample data and to associate data with reference values.” (*Id.*) The Examiner finds that:

[O]ne would have recognized the advantages of prediction systems that include various types of data such that the systems could be utilized to manipulate data for prognostic applications, such as generating a disease free survival curve for various diagnoses. The goal of Gehrman et al., for example, is to generate a robust prediction methodology using said computer implementations. The goal of Kattan et al. for example, is to predict patient outcomes using accumulated data etc... It would be obvious to use the well-known technique of disease free survival graph generation in such methods for statistical representation of data and ease of user interface.

(Final Action 12; Ans. 11.)

We agree with the Examiner’s factual findings and conclusion that the prior art renders the claimed apparatus for supporting diagnosis of cancer obvious.

Appellants argue that while Gehrman, Kattan, and Kim are in the field of cancer diagnosis/classification, none of Gehrman, Kattan or Kim teach generating a disease-free survival graph for diagnosis support information of cancer or regenerating such a graph using a changed

reference value and that nothing in Killoren Clark, Kenmochi or Nozaki, suggest the foregoing though they include teachings concerning changeable reference values and making determinations before and after the changes are made to the reference value. (Appeal Br. 13–16.) Appellants further argue that, while Kohrt and Ravdin teach determinations of disease-free survival in cancer, neither “discloses or suggests that on the same screen that displays a sample data chart and a reference value indicator, there is generated a disease free survival graph, much less a disease free survival graph for a diagnosis support information of cancer based on the sample data contained in those regions partitioned by the reference value that are associated with the diagnosis support information,” nor do either “disclose[] re-generating the disease free survival graph on the same screen when the reference value is changed so as to allow the user to change the reference value until a desired disease free survival graph is generated.” (Appeal Br. 16–17.)

The foregoing argument is not persuasive. “Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Appellants do not contest that the prior art teaches cancer diagnosis involving producing disease-free survival information and presenting the analytical results graphically (Ravdin 985 and Fig. 3; Kohrt 908–914), or that Ravdin provides for a display screen that has four major components including a graphical format of outcomes “showing ‘No additional Therapy’ input and ‘Endocrine Therapy’ input

comparisons in the same window along with general efficacy information, i.e., reference information (Ans. 18; Ravdin Fig. 3). And we disagree with Appellants that the Examiner has not explained “where or how the relied upon combination taught or suggested all of the features of claim 1.”

(Appeal Br. 17–18.) As the Examiner pointed out:

Ravdin et al. specifically teaches that resulting graphs allow for simultaneous viewing of outcomes for survival in terms of survival curves. The bar graphs reflect projections based on various scenarios and are comparative in nature (page 987, column 1).

(Ans. 18.) Appellants also do not contest that the prior art relied on by the examiner teaches “computerized systems that execute methods that acquire measurement value and clinical information, compare the measurement and reference values, and display for presenting reference and measurement data,” which are analogous to the claimed apparatus. (Ans. 17.) Nor do Appellants contest that the prior art teaches improving analytical technology by user’s being able to update and change reference values. (*Id.*) We agree with the Examiner that the combination of references together make prima facie obvious generating and regenerating, after update, graphs depicting disease-free survival and displaying that information on the same screen as reference information.

Appellants’ argument that the claimed invention “offer[s] significant advantages” because “the user can appropriately change the reference value so that the recurrence rate after elapse of five years takes a value within a predetermined range while looking at the survival curve, and as a result, can set a reference value having a high determination accuracy” (Appeal Br. 18) is also unpersuasive. The claim does not require instructions related to

Appellants' asserted advantage. It has long been established that unclaimed features cannot impart patentability to claims. *See In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998); *and In re Self*, 671 F.2d 1344, 1348 (CCPA 1982). Furthermore, Appellants point to no factual evidence supporting the alleged advantage. "Attorney[s]' argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Claims 2–9 and 11–14 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

#### SUMMARY

We affirm the rejection of claims 1–9 and 11–14 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

We affirm the rejection of claims 1–9 and 11–14 under 35 U.S.C. § 103 as unpatentable over Gehrman, or Kattan, or Kim, and Killoren Clark, or Kenmochi, and/or Nozaki, and Kohrt, or Ravdin.

#### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED